

### **EXAMINER'S AMENDMENT**

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 26 March 2009, Robert Traver requested an extension of time for 1 MONTH(S) and authorized the Director to charge Deposit Account No. 19-1970 the required fee for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

**The title:**

The title of the application, i.e. "Diagnosis and Monitoring of Disease" was deleted and replaced by --Diagnosis of multiple sclerosis with diketopiperazines--.

**In the claims:**

In claim 47, lines 7-10 were deleted, i.e. "(i) a compound having a mass of about 175 as determined by liquid chromatography and mass spectrometry; (ii) a compound having a mass of about 145 as determined by liquid chromatography and mass spectrometry;" was deleted.

In claim 47, line 11, "(iii)" was deleted and replaced by --(i)--.

In claim 47, line 12, "(iv)" was deleted and replaced by --(ii)--.

In claim 47, line 13, "(v)" was deleted and replaced by --(iii)--.

In claim 47, line 13, "two or more" was deleted and replaced by --both--.

In claim 47, line 14, "wherein:" was deleted and replaced by --wherein--.

In claim 47, lines 15-16 were deleted, i.e. "the absence of compound (i), compound (ii) or both compounds (i) and (ii) from the biological sample is indicative of MS; and" was deleted.

Claim 48 was canceled.

Claim 49 was canceled.

Claim 50 was canceled.

In claim 51, line 1, "Claims" was deleted and replaced by --Claim--.

In claim 54, line 1, "47-53" was deleted and replaced by --47 and 51-53--.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jackson et al. (Neurology. 1986 Sep;36(9):1218-23; citation 124 on IDS dated 27 August 2008) teaches the measurement of His-Pro-DKP in spinal cord tissue and cerebrospinal fluid of postmortem amyotrophic lateral sclerosis patients.

Prasad et al. (Neuropeptides. 1991 Nov;20(3):187-90; citation 134 on IDS dated 27 August 2008) teaches that increased His-Pro-DKP is present in the cerebrospinal fluid of schizophrenia patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch, Ph.D.  
Patent Examiner  
Art Unit 1649  
27 March 2009

/Daniel E. Kolker/  
Primary Examiner, Art Unit 1649  
March 30, 2009